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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,671	12/10/2001	Otfried Kistner	V-262.00	2215

7590 10/06/2004

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EXAMINER
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CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,671	<b>Applicant(s)</b> KISTNER ET AL.	
	<b>Examiner</b> Stacy B Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11,14-17 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-11,14-17 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2004 has been entered.

### *Claim Rejections - 35 USC § 103*

2. Claims 1-4, 7-11, 14-17 and 27-31 are rejected under 35 U.S.C., 103(a) as unpatentable over Dubensky Jr. *et al.* (5,789,245, herein, "Dubensky") in view of Yu *et al.* (reference AM from IDS, herein, "Yu"), both of record, and further in view of Harley *et al.*, (*Clin. Micro. Reviews*, 2001, 14(4):909-932, herein, "Harley"). The claims as amended are drawn to a method for producing purified Ross River Virus (RRV) antigen/immunogenic compositions comprising the steps of infecting a cell culture with RRV, incubating the infected cell culture, harvesting the RRV produced, filtering through two filters and purifying the virus antigen. The first filter has a pore size of between about 0.3 and about 1.5 microns. The second filter has a pore size of between 0.1 and 0.5 microns.

In the interview with Ms. Brigitte Hajos and Mr. Kevin Bastian, attorneys of record, on September 1, 2004, the size of the second filter in the claimed method was discussed. Applicant argues that Dubensky fails to teach the use of a second filter having a pore size of between 0.1 and 0.5 microns. Dubensky's method of large-scale production of alphavirus vectors, including

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Ross River Virus, uses a second filter having a pore size of 0.65 microns, which differs from the claimed method by 0.15 microns.

Applicant's arguments have been carefully considered but fail to persuade. While the amended claims recite a filter pore size range of between 0.1 and 0.5 microns, which differs from Dubensky's filter size of 0.65 by 0.15 microns, it would have been obvious to use a filter pore size of less than 0.65 microns. Given that the diameter of an alphavirus is known, the determination of the particular filter pore size ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization. One would have been motivated to use a smaller filter pore size in order to obtain a highly purified product. One would have had a reasonable expectation of success that Ross River Virus would have been filtered through a pore size of 0.1 to 0.5 because the size of an alphavirus is about 400 Å in diameter (Harley *et al.*, *Clin. Micro. Reviews*, 2001, 14(4):909-932, particularly page 911, second column, of record). Therefore, the claimed filter pore size is obvious in view of the known size of the virus and the ability of one of ordinary skill in the art to optimize a known process.

### ***Conclusion***

3. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*SPC*

Stacy B. Chen  
September 27, 2004

*James C. Housel*  
JAMES HOUSEL 10/1/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600